UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In Re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

THIS DOCUMENT RELATES TO:
(State of Montana v. Abbott Labs., Inc., et al., 02-CV-12084-PBS)

X

: MDL NO. 1456
: Master File No. 01-CV-12257-PBS
: Judge Patti B. Saris

ANSWER AND DEFENSES OF DEFENDANT ASTRAZENECA PHARMACEUTICALS LP AND ZENECA INC. TO THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT

Defendants AstraZeneca Pharmaceuticals LP ("AZPLP") and Zeneca Inc.¹ (collectively "AstraZeneca"), through its undersigned counsel, answer the State of Montana's Second Amended Complaint (the "SAC") served via Verilaw on August 1, 2003, in the above-captioned action as follows:

I. INTRODUCTION

1. Admits that Plaintiff purports to bring this case as alleged in paragraph 1, but denies the allegations in paragraph 1, specifically denies the existence of or participation in an "Average Wholesale Price Inflation Scheme," denies that there exists any basis in fact or law for the institution or maintenance of this action against AstraZeneca, and otherwise denies knowledge or

¹ The entity listed as AstraZeneca US does not exist. Although AstraZeneca PLC is referenced in the SAC, it is not named as a defendant.

information sufficient to form a belief as to the truth of the allegations in paragraph 1 as to the other parties.

- 2. Admits that AZPLP manufactures, sells, and/or distributes pharmaceutical products in the United States. To the extent the allegations in paragraph 2 refer to statutory or regulatory programs, the statutes, regulations, and other sources regarding those programs speak for themselves, and any characterizations thereof are denied. AstraZeneca denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 as to the other parties.
- 3. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3, except admits that the development of new drugs can benefit individuals.
- 4. Denies the allegations in paragraph 4 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 as to the other parties.
- 5. Denies the allegations in paragraph 5, except admits that some private and public drug reimbursement systems reimburse physicians and pharmacies based upon the AWP for some prescription drugs, as published and reported by various independent third-party publications, but denies the remaining allegations in paragraph 5 to the extent they are directed at AstraZeneca, and

otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 as to the other parties.

- 6-7. Denies the allegations in paragraphs 6-7 to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme," and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 6-7 as to the other parties and entities.
- 8-10. Denies the allegations in paragraphs 8-10 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 8-10 as to the other parties.
- 11-12. Plaintiff's "Best Price" claims against AstraZeneca have been dismissed by Court Order or released by Plaintiff pursuant to a settlement agreement executed in 2003. Accordingly, no answer is required and none is made. To the extent an answer is required, AstraZeneca denies the allegations in paragraphs 11-12.
- 13. Denies the allegations in paragraph 13 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 13 as to the other parties.
- 14-17. Denies the allegations in paragraphs 14-17 to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme" or "Best Price Scheme," as alleged

in paragraphs 14-17, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 14-17 as to the other parties.

- 18. Admits that Plaintiff seeks to recover costs as actual damages and/or restitution, but denies the allegations of paragraph 18 and denies that there exists any basis in fact or law for the institution or maintenance of this action against AstraZeneca.
- 19-20. Denies the allegations in paragraphs 19-20 to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme," as alleged in paragraph 19, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 19-20 as to the other parties.
- 21. Admits that Plaintiff seeks restitution through its *parens* patriae and statutory powers, but denies the allegations in paragraph 21, and denies that there exists any basis in fact or law for the institution or maintenance of this action against AstraZeneca.
- 22. States that paragraph 22 consists of Plaintiff's characterizations of this action, to which no response is required, and otherwise denies the allegations in paragraph 22, and denies that there exists any basis in fact or law for the institution or maintenance of this action against AstraZeneca.
- 23. Denies the allegations in paragraph 23 to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme" or "Best Price Scheme," as alleged in paragraph

23, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 as to the other parties.

II. PARTIES

A. Plaintiff

- 24. Admits that the State of Montana purports to bring this action as alleged in paragraph 24, but denies any allegations or characteristics in paragraph 24, denies that Plaintiff has any basis in fact or law to maintain this action against AstraZeneca, and refers to the referenced statutes for their content, which speak for themselves.
- 25-28. Refers to the relevant statutes and regulations governing the Montana Medicaid Program for their content, which speak for themselves, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 25-28.

B. Defendants

- 29. Denies the allegations in paragraph 29 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 as to the other parties.
- 30. Admits that AZPLP sells and/or distributes products in the United States, including Montana, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30 as to the other parties and entities.

1. Abbott

31-32. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 31-32.

2. Amgen

33-34. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 33-34.

3. AstraZeneca

- 35. Denies the allegations in paragraph 35, except admits that Zeneca Inc. is a Delaware corporation with its principal place of business located at 1800 Concord Pike, Wilmington, Delaware, and further admits that Zeneca Inc. is an indirect subsidiary of AstraZeneca PLC, a public limited liability company organized under the laws of England and Wales.
 - 36. Denies the allegations in paragraph 36.
- 37. Denies the allegations in paragraph 37, except admits that AZPLP is a Delaware corporation, with its principal place of business located at 1800 Concord Pike, Wilmington, Delaware, and further admits that AZPLP is an indirect subsidiary of AstraZeneca PLC, a public limited liability company organized under the laws of England and Wales.
- 38. Denies the allegations in paragraph 38, except admits that Plaintiff purports to refer collectively to the entities listed as "AstraZeneca."
- 39. Denies the allegations in paragraph 39, except admits that AZPLP manufactures several drugs which may, under certain circumstances, be reimbursable under the Montana Medicaid Program.

4. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

40-45. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 40-45.

5. Baxter

46-49. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 46-49.

6. Bayer

50-52. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 50-52.

7. The Boehringer Group (Boehringer, Ben Venue, Bedford)

53-57. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 53-57.

8. Braun

58-60. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 58-60.

9. The BMS Group (Oncology Therapeutics, Apothecon)

61-66. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 61-66.

10. Dey

67-69. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 67-69.

11. The Fujisawa Group (Fujisawa Healthcare, Fujisawa USA)

70-73. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 70-73.

12. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

74-79. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 74-79.

13. Immunex

80-82. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 80-82.

14. The Johnson & Johnson Group (J&J, Centocor, Janssen, McNeil, Ortho)

83-88. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 83-88.

15. Novartis

89-90. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 89-90.

16. Pfizer, Inc.

91-92. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 91-92.

17. The Pharmacia Group (Pharmacia and Pharmacia & Upjohn)

93-96. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 93-96.

18. The Schering-Plough Group (Schering Plough & Warrick)

97-100. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 97-100.

19. The Sicor Group (Sicor and Gensia)

101-106. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 101-106.

20. TAP

107-109. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 107-109.

21. Watson

110-111. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 110-111.

III. PRESCRIPTION DRUG SPENDING

- 112. Denies the allegations in paragraph 112.
- 113-117. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 113-117, and refers to the *Kaiser Family Foundation, Prescription Drug Trends: A Chartbook Update*, dated November 2001, and the *Kaiser Family Foundation, Prescription Drug Trends: A Chartbook*, dated July 2000, referenced in paragraphs 113-117, for their content, which speak for themselves.
- 118. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 118, and refers to the *Kaiser Family*

Foundation, Medicare And Prescription Drugs Fact Sheet, dated April 2003, for its content, which speaks for itself.

- 119-121. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 119-121, and refers to the *Kaiser Family Foundation, Prescription Drug Trends: A Chartbook Update*, dated November 2001, and the *Kaiser Family Foundation, Prescription Drug Trends: A Chartbook*, dated July 2000, referenced in paragraphs 119-121, for their content, which speak for themselves.
- Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 122.
- 123. Denies the allegations in paragraph 123 to the extent that they are directed at AstraZeneca, specifically denies that AstraZeneca has committed any "fraud," and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 123 as to the other parties.

IV. THE PRESCRIPTION DRUG MARKET

- 124. Admits the allegation in paragraph 124 that specialized terms exist in the pharmaceutical industry, but denies the remaining allegations in paragraph 124, and specifically denies the existence of or participation in "frauds and schemes" as alleged in paragraph 124.
 - 125-127. Admits the allegations in paragraphs 125-127.
- 128. Admits the allegation in paragraph 128 that a brand-name drug may or may not have a generic equivalent, depending upon a variety of factors, including whether the patent has expired and whether a generic manufacturer has

produced a generic version, but denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 128.

- 129. Denies the allegations in paragraph 129, but admits that AZPLP distributes most of its products through one or more of several different types of entities, including, wholesalers, retailers, hospitals, and providers, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 129 as to other parties.
- 130. Denies knowledge or information sufficient to form a belief as to the allegations in paragraph 130, and refers to the *Kaiser Family Foundation*, *Prescription Drug Trends: A Chartbook*, dated July 2000, referenced in paragraph 130, for its content, which speaks for itself.
- 131. Denies the allegations in paragraph 131, but admits that Wholesale Acquisition Cost ("WAC") is generally the list price for sales by manufacturers to wholesalers.
- 132. Admits some private and public drug reimbursement systems reimburse based upon AWP, but denies knowledge or information sufficient to form a belief as to the allegations stated in the first sentence of paragraph 132, and denies the remaining allegations in paragraph 132.
- 133. Denies knowledge or information sufficient to form a belief as to the allegations in paragraph 133, and refers to the *Kaiser Family Foundation*, *Prescription Drug Trends: A Chartbook*, dated July 2000, referenced in paragraph 133, for its content, which speaks for itself.

- 134-135. Denies the allegations in paragraphs 134-135 to the extent they are directed at AstraZeneca and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 134-135 as to the other parties.
- 136-137. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 136-137.
- 138. Admits the allegations in the first sentence of paragraph 138, but denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 138.
- 139. Denies knowledge or information sufficient to form a belief as to the allegations in paragraph 139, and refers to the *Kaiser Family Foundation*, *Prescription Drug Trends: A Chartbook*, dated July 2000, referenced in paragraph 139, for its content, which speaks for itself.
- 140. Denies the allegations in paragraph 140 to the extent they are directed at AstraZeneca and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 140 as to the other parties.
- 141. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 141.

V. GOVERNMENT REIMBURSEMENT SYSTEMS FOR PRESCRIPTION DRUGS

142-144. Admits the allegations in paragraphs 142-144.

- 145. Refers to the *CCH* Article, "Medicare Explained," referenced in paragraph 145 for its content, which speaks for itself, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 145.
- 146. Admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth in 42 C.F.R. § 405.517, which is referenced in paragraph 146, and refers to 42 C.F.R. § 405.517 for its content, which speaks for itself.
- 147. Denies the allegations in the first sentence of paragraph 147 insofar as it contains material in quotation marks, the source of which is not identified. AstraZeneca further denies the second sentence of paragraph 147 insofar as 42 C.F.R. § 405.517 contains no reference to a "ceiling" on reimbursement amounts.
- 148. Denies knowledge or information sufficient to form a belief as to the truth of the allegation regarding the date of the amendment, and otherwise admits the allegations in paragraph 148.
- 149-150. Admits that the Medicare Program has publicly announced that it would use the AWP published in independently produced compendia as the basis for reimbursement, and refers to Program Memorandum AB-99-63, referenced in these paragraphs, for its content, which speaks for itself.
- 151. Admits that there are no regulations describing how AWPs are to be calculated, or regulatory process for approving them, denies the remaining allegations in paragraph 151 to the extent that they are directed at AstraZeneca,

and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 151 as to the other parties.

- 152-153. Admits the allegations in paragraphs 152-153, except denies that a 20% co-payment is always paid by a Medicare Part B beneficiary.
- 154-156. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 154-156, and refers to *Medicaid and Prescription Drugs: An Overview*, dated October 2000, referenced in paragraphs 154-156, for its content, which speaks for itself.
- 157. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 157, and refers to *Kaiser Commission* on Medicaid and the Uninsured, Medicaid Facts: Medicaid and Prescription Drugs, dated October 2000, referenced in paragraph 157, for its content, which speaks for itself.
- 158. Refers to the statutes and regulations governing the Medicare and Medicaid Programs for their content, which speak for themselves.
- 159. Refers to 42 C.F.R. § 440.120 and the statutes and regulations governing the Montana Medicaid Program, for their content, which speak for themselves.
- 160-161. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 160-161, and refers to *Outpatient Prescription Drug Benefits Under Medicaid: Detailed Case Studies*, dated October 2001, referenced in paragraphs 160-161, for its content, which speaks for itself.

- 162. Refers to Mont. Admin. R. 37.86.1105, Mont. Admin. R. 37.86.1101(3), 42 C.F.R. 447.331-32, and *Montana Department of Public Health & Human Services, Prescription Drug Program*, dated May 2002, for their contents, which speak for themselves, and otherwise denies knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 162.
- 163. Refers to the statutes and regulations governing the Montana Medicaid Program for their contents, which speak for themselves.

VI. AWP ALLEGATIONS

- Denies the allegations in paragraph 164, but admits that AWPs play a role in various prescription drug reimbursement systems that operate in the United States.
- 165. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 165, except admits that prescription drugs are dispensed to patients by different types of medical providers including physicians, hospitals and pharmacies.
- 166. Admits that some private and public drug reimbursement systems reimburse physicians and pharmacies for certain prescription drugs based upon AWP, but otherwise denies the allegations in paragraph 166 to the extent they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 166 as to the other parties and entities.

- 167. Admits that several independently produced compendia periodically publish AWPs for various prescription drugs, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 167.
- 168-169. Denies the allegations in paragraphs 168-169 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 168-169 as to the other parties and entities, except admits that prior to January 2002, AstraZeneca reported suggested AWPs for certain pharmaceuticals to independently produced pricing compendia, and refers to the Foreward to the 1999 edition of the *Red Book*, the June 1996 *Dow Jones* news article, and the Dey Complaint referenced in paragraph 168, for their content, which speak for themselves, but denies any characterization of these documents.
- 170-171. Denies the allegations in paragraphs 170-171 to the extent they are directed at AstraZeneca, and refers to the April 2003 Office of the Inspector General ("OIG") Report, referenced in paragraphs 170-171, for its content, which speaks for itself, but denies any characterization of this document.
- 172. Denies the allegations in paragraph 172 to the extent they are directed at AstraZeneca, specifically denies the existence of, or participation in the fraudulent or unlawful manipulation of AWPs, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 172 as to the other parties.

VII. THE PURPORTED AWP INFLATION SCHEME

- 173-174. Denies the allegations in paragraphs 173-174 to the extent they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme" as alleged in paragraph 174, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 173-174 as to the other parties and entities.
- 175. Denies the allegations in paragraph 175 to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme" as alleged in paragraph 175, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 175 as to the other parties.
- 176-180. Denies the allegations in paragraphs 176-180 to the extent they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "scheme" as alleged in paragraphs 177, 178 and 180, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 176-180 as to the other parties, except admits that prior to January 2002, AstraZeneca reported suggested AWPs for certain pharmaceuticals to independently produced pricing compendia.
- 181. Denies the allegations in paragraph 181 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 181 as to the other parties.

- 182. Denies the allegations in paragraph 182 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 182 as to the other parties.
- 183-184. Denies the allegations in paragraphs 183-184 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 183-184 as to the other parties.
- 185-200. Denies the allegations in paragraphs 185-200 to the extent they are directed at AstraZeneca, specifically denies the existence of, or participation in, any "AWP Inflation Scheme," as alleged in paragraphs 185-200, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 185-200 as to the other parties and entities.
- 201-202. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 201-202.
- 203-208. Denies the allegations in paragraphs 203-208 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 203-208 as to the other parties and entities.
- 209. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 209, and refers to *The Wall Street Journal* article, dated March 30, 2003, referenced in paragraph 209, for its content, which speaks for itself.

- 210. Denies the allegations in paragraph 210, except admits that the federal government has been investigating drug marketing and pricing practices.
- 211-212. Denies the allegations in paragraphs 211-212 to the extent they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "scheme," as alleged in paragraph 211, denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 211-212 as to other parties and entities, and refers to the September 28, 2000 letter authored by Congressman Pete Stark, referenced in paragraphs 211-212, for its content, but denies any characterization of this document.
- 213. Denies the allegation in paragraph 213, except admits that the federal government has been investigating drug marketing and pricing practices.

E. EXAMPLES OF ALLEGED SPECIFIC CONDUCT

214-215. Denies the allegations in paragraphs 214-215 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 214-215 as to the other parties, except admits that Appendix A purports to be a list of drugs that Plaintiff alleges are subject to its asserted claims.

1. Abbott

216-233. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 216-233.

2. Amgen

234-248. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 234-248.

3. AstraZeneca

- 249-250. Denies the allegations in paragraphs 249-250, specifically denies the existence of, and participation in, any "scheme," as alleged in paragraph 249, and denies that there exists any basis in fact or law for the institution or maintenance of this action against AstraZeneca, except admits that Plaintiff alleges that the following drugs are at issue in this action: Accolate, Arimidex [misspelled Armidex in the SAC], Atacand, Atacand HCT, Casodex, Diprivan, Entocort, Nexium, Nolvadex, Prilosec, Pulmicort, Rhinocort, Seroquel, Toprol, Zestril, Zoladex, and Zomig.
- 251. Denies the allegations in paragraph 251, and refers to the undated memorandum referenced in paragraph 251 for its content, which speaks for itself, but denies any characterization of this document.
- 252. Denies the allegations in paragraph 252, and specifically denies the existence of any "scheme," as alleged in paragraph 252.
- 253. Denies the allegations in paragraph 253, and refers to the Guide to Coverage and Reimbursement referenced in paragraph 253 for its content, which speaks for itself, but denies any characterization of this document.
- 254-256. Denies the allegations in paragraphs 254-256, and refers to the documents referenced in paragraphs 254-256 for their content, which speak for themselves, but denies any characterization of these documents.
 - 257. Denies the allegations in paragraph 257.

- 258-261. Denies the allegations in paragraphs 258-261, and refers to the documents referenced in paragraphs 258-261 for their content, which speak for themselves, but denies any characterization of these documents.
 - 262. Denies the allegations in paragraph 262.
- 263-264. Denies the allegations in paragraphs 263-264, specifically denies the existence of, and participation in, any "scheme," as alleged in paragraph 264, and refers to the document referenced in paragraphs 263-264 for its content, which speaks for itself, but denies any characterization of this document.
- 265. Denies the allegation in paragraph 265, specifically denies the existence of, and participation in, any "scheme," as alleged in paragraph 265, and refers to the document referenced in paragraph 265 for its content, which speaks for itself, but denies any characterization of this document.
- 266. Denies the allegations in paragraph 266, and refers to the September 2001 GAO Report, referenced in paragraph 266, for its content, which speaks for itself, but denies any characterization of this document.
 - 267. Denies the allegations in paragraph 267.
- 268. Denies the allegations in paragraph 268, and refers to the document dated July 17, 1995 referenced in paragraph 268 for its content, which speaks for itself, but denies any characterization of this document.
- 269. Denies the allegations in paragraph 269, and refers to the indictment referenced in paragraph 269 for its content, but denies any characterization of this document.

- 270. Admits the allegations in paragraph 270.
- 271. Denies the allegations in paragraph 271.
- Denies the allegations in paragraph 272, except admits that in June 2003, AZPLP entered into a settlement agreement with certain Federal and State government entities.
 - 273. Denies the allegations in paragraph 273.

4. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

274-295. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 274-295.

5. Baxter

296-312. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 296-312.

6. Bayer

313-331. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 313-331.

7. The Boehringer Group

332-346. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 332-346.

8. B. Braun

347-363. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 347-363.

9. The BMS Group (Bristol-Myers, OTN and Apothecon)

364-385. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 364-385.

10. Dev

386-409. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 386-409 (and misnumbered paragraph 15).

11. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)

410-422. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 410-422.

12. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

423-464. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 423-464.

13. Immunex

465-480. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 465-480.

14. The Johnson & Johnson Group (J&J, Centocor and Ortho)

481-495. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 481-495.

15. Novartis

496-503. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 496-503.

16. Pfizer

504-511. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 504-511.

17. The Pharmacia Group (Pharmacia and P&U)

512-531. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 512-531.

18. The Schering-Plough Group (Schering-Plough and Warrick)

532-549. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 532-549.

19. The Sicor Group (Sicor, Gensia and Gensia Sicor)

550-567. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 550-567.

20. TAP

568-588. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 568-588.

21. Watson

589-602. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 589-602.

VIII. DEFENDANTS' PURPORTED "BEST PRICE" FRAUDS

603-634. Plaintiff's "Best Price" claims against AstraZeneca have been dismissed by Court Order or released or discharged by Plaintiff pursuant to a settlement agreement. Accordingly, no response is required to paragraphs 603-

634, and to the extent any response is required, AstraZeneca denies the allegations in paragraphs 603-634.

IX. DEFENDANTS' PURPORTED CONCEALMENT OF THE TRUTH

- 635. Denies the allegations in paragraph 635 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 635 as to the other parties.
- directed at AstraZeneca, except admits that AZPLP sells its products in a competitive market and consequently, that it takes steps to keep certain information relating to its pharmaceuticals confidential, and refers to the CMS Health Care Industry Market Update dated January 10, 2003, referenced in paragraph 636, for its content, which speaks for itself, but denies any characterization of this document, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 636 as to the other parties.
- 637-640. Denies the allegations in paragraphs 637-640 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 637-640 as to the other parties.
- 641. Denies the allegations in paragraph 641 and denies that there exists any basis in fact or law for the institution or maintenance of this action

against AstraZeneca. AstraZeneca further denies that the Plaintiff did not receive inquiry or other notice of the issues associated with reliance on AWP as a pricing benchmark; on the contrary, such issues were well known before Plaintiff brought this suit. In addition, to the extent that paragraph 641 contains conclusions of law, AstraZeneca states that no response is required.

642-643. States that paragraphs 642-643 contain conclusions of law, to which no response is required, otherwise denies the allegations in paragraphs 642-643 to the extent they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 642-643 as to the other parties.

X. ALLEGED DAMAGES SUSTAINED BY THE STATE OF MONTANA, PATIENTS AND THIRD-PARTY PAYORS

- 644. Denies the allegations in paragraph 644 to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme," and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 644 as to the other parties.
- 645. Admits the allegations in paragraph 645, except denies that a 20% co-payment is always paid by a Medicare beneficiary.
- directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 646 as to the other parties.

- 647. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 647.
- directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief truth of the allegations in paragraph 648 as to the other parties.
- 649. Admits that Medicare beneficiaries can obtain supplemental insurance to cover costs not paid by Medicare, but denies the remaining allegations in paragraph 649, and specifically denies the existence of, or participation in, any "AWP Inflation Scheme."
- 650-653. Denies the allegations in paragraphs 650-653 to the extent they are directed at AstraZeneca, specifically denies the existence of, or participation in, any "AWP Inflation Scheme," and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 650-653 as to the other parties and entities.

XI. CLAIMS FOR RELIEF

COUNT I

ALLEGED DECEPTIVE TRADE PRACTICES (Violations of Mont. Code Ann. §§ 30-14-101-1414)

CLAIM FOR DAMAGES ALLEGEDLY CAUSED TO MONTANA RESIDENTS

654. Answering for paragraph 654, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 653.

- 655. Denies that Plaintiff is entitled to maintain this action as alleged or to obtain any relief against AstraZeneca, and specifically denies the existence of, or participation in, any "AWP Inflation Scheme," as alleged in paragraph 655.
- 656. States that paragraph 656 (and its subparts) consists of conclusions of law to which no response is required, otherwise denies the allegations in paragraph 656 (and its subparts) to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 656 (and its subparts) as to the other parties.
- 657-659. Denies the allegations in paragraphs 657-659 to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 657-659 as to the other parties.
- 660. States that paragraph 660 consists of a conclusion of law to which no response is required, otherwise denies the allegations in paragraph 660 to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 660 as to the other parties. AstraZeneca further denies that Plaintiff has suffered any damages or injuries as alleged in paragraph 660.
- 660a. Denies that Plaintiff is entitled to a judgment or any other relief requested in its prayer for relief, as stated in the unnumbered paragraph following paragraph 660 of the SAC.